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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,712	12/12/2000	D. Wade Walke	LEX-0109-USA	5587

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[REDACTED] EXAMINER

LI, RUIXIANG

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1646

9

DATE MAILED: 12/06/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)
	09/735,712	WALKE ET AL.
	Examin r	Art Unit
	Ruixiang Li	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Objection to the Specification

1. The disclosure is objected because of the lack of adequate description of the sequence listing. Appropriate correction is required.

Rejections—35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 1-4 are drawn to nucleic acid molecules that encode polypeptides with sequence similarity to CD20 proteins and IgE receptors. The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a “real world” context of use for the claimed invention which does not require further research.

The instant disclosure asserts numerous utilities for the claimed invention solely based upon the homology of the polypeptides encoded by the polynucleotides to CD20 proteins and IgE receptors (page 2, Introduction; page 15,

3rd paragraph). The disclosure does not provide any experimental data or information on whether the claimed polypeptides actually function like IgE receptor and CD2. The state of the art in protein science indicates that it is impossible to predicate protein functions solely with structure homology. "Identical structural features, or folds, in proteins can perform many different roles and so using only homology to predict function is a very dangerous and difficult mission" (Apoorva Mandavilli, *Protein folds shield different Roles*, BioMednet News, November 1, 2001). Thus, all the asserted utilities in the disclosure based upon the protein homology are not specific and substantial.

The specification discloses the asserted utilities of the claimed polynucleotides as PCR primers for screening libraries (page 5, 1st paragraph; page 10, 3rd paragraph), as hybridization probes for assessing gene expression patterns (page 5, 2nd paragraph; page 6, 1st paragraph) and identification of novel molecular targets for drug discovery (page 7, 2nd paragraph), or as antisense molecules for gene regulation (page 8, 2nd paragraph). The disclosure further asserts that the polypeptides encoded by the claimed polynucleotides can be used to generate antibodies (page 15, 4th paragraph). However, such uses are all considered research uses only designed to identify a particular function of the claimed molecules and are not a substantial utility. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility." Moreover, such uses are not specific to the instant molecule but applicable to any polynucleotides or polypeptides.

In addition, the specification asserts that the claimed polynucleotides can be used to identify mutations associated with a particular disease or in diagnostic/prognostic assays (page 7, 3rd-4th paragraphs). The specification also asserts that the claimed polynucleotides, polypeptides, fusion proteins, and antibodies “can be useful” for the diagnosis of a disease or for screening drugs (page 14, 2nd paragraph; page 15, 4th paragraph; page 23, 2nd paragraph). The specification further asserts that the claimed molecules can be used as therapeutic reagents to treat a disease (page 14, 3rd paragraph; page 15, 4th paragraph—page 16, 1st paragraph). These asserted utilities are not specific and substantial because they do not identify or reasonably confirm a “real world” context of use. The specification does not disclose any diseases or conditions that are associated with the claimed molecules. Clearly, further research would be required to identify a disease that is associated with the claimed molecules or a disease that can be treated with the claimed molecules. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification’s disclosure of the properties of a material. The assertion that the polypeptides encoded by the claimed polynucleotides are homologous to CD20 proteins and IgE receptors (page 2, Introduction; page 15, 3rd paragraph) does not endow the claimed protein with a specific and substantial

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utility. No art of record discloses or suggests any property or activity for the claimed protein such that another non-asserted utility would be well-established for the claimed molecules.

4. Claim 1-4 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, even if the polynucleotide of SEQ ID NO: 1 encoding the claimed polypeptide of SEQ ID NO: 2 were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the claimed invention comprising a genus of at least 24 contiguous nucleotides of SEQ ID NO:

1.

The factors to be considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 1 recites a genus of polynucleotides of any size that has at least 24 contiguous nucleotides of SEQ ID NO: 1. However, other than SEQ ID NO: 1 that encodes SEQ ID NO: 2, the disclosure has not provided sufficient guidance and

information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claim. The disclosure has not shown (i) which portions of SEQ ID NO: 1 are critical to the activity of the protein of SEQ ID NO: 2; and (ii) what modifications (e.g., substitutions, deletions or additions) one can make to SEQ ID NO: 1 will result in protein mutants with the same functions as the protein of SEQ ID NO: 2. The state of the art (See, e.g., Ngo, et al, *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz, et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495) is such that the relationship between sequence of a protein and its activity is not well understood and is not predictable. Excising out portions of a protein or modifications to a protein, e.g., by substitutions or deletions, would often result in deleterious effects to the overall activity and effectiveness of the protein.

Accordingly, the disclosure fails to enable such a myriad of the claimed polynucleotides that not only vary substantially in length but also in amino acid composition and to provide any guidance to those skilled generally on how to make and use the claimed genus of polynucleotides. Thus, it would require undue experimentation for one skilled in the art to make and use the claimed genus of polynucleotides embraced by the instant claim.

Claim Rejections—35 USC § 112, 1st paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification discloses a nucleotide sequence set forth in SEQ ID NO: 1. However, claim 1 recites a genus of polynucleotides with at least 24 contiguous nucleotides set forth in SEQ ID NO: 1. Thus, it encompasses virtually any random sequence of any length as long as it has a stretch of at least 24 consecutive nucleotides that is the same as SEQ ID NO: 1.

The instant disclosure of a single species of nucleic acid of SEQ ID NO: 1 does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant disclosure fails to provide sufficient description information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions that are critical to the structure and function of the genus claimed. There is no description of the sites at which variability

may be tolerated and there is no information regarding the relation of structure to function. Furthermore, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed polynucleotides as being identical to those instantly claimed.

Due to the breadth of the claim genus and lack of the definitive structural or functional features of the claimed genus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus.

Claim Rejections—35 USC § 112, 2nd paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1 and 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it recites the term of "NHP polynucleotide". It is unclear what are the metes and bounds of "NHP polynucleotide" and what characterizes "NHP polynucleotide". The term "NHP (novel human protein) polynucleotide is indefinite in that it only describes the polynucleotide encoding a protein of interest by an arbitrary name. While such arbitrary name itself may have some notion of the activity of the protein, there is nothing recited in the claim that distinctly claims the protein. Other researchers working in the same field may isolate the same protein and give it an entirely

different name. Thus, claiming a protein by a particular name given to the protein by various workers in the field fails to distinctly claim the protein. Applicants should particularly point out and distinctly claim the protein by its structural and functional characteristics.

Claim 2 is indefinite because it recites "under stringent conditions", but without giving the specific conditions in the claim.

Claim Rejections—35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al. (EMBL, accession No: AA436088, November 9, 1997). Hillier et al. teach a nucleotide sequence comprising at least 24 contiguous nucleotides of SEQ ID NO: 1 (See attached sequence alignment), meeting the limitation of claim 1.
11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Database EMBL, Accession NO: AI149899 (November 10, 1998; IDS paper No: 8), which teaches a nucleotide sequence comprising at least 24 contiguous nucleotides of SEQ ID NO: 1, meeting the limitation of claim 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
December 3, 2001


YVONNE EYLER, PH.D
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